UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE CHECKPOINT THERAPEUTICS SECURITIES LITIGATION	24 Civ. 2613 (PAE) OPINION & ORDER

PAUL A. ENGELMAYER, District Judge:

Lead plaintiff Hamilton Bailey brings this putative class action under the federal securities laws against defendant Checkpoint Therapeutics, Inc. ("Checkpoint"), a biopharmaceutical company, and its CEO James F. Oliviero (collectively with Checkpoint, "defendants"). The putative class consists of all persons (other than defendants) who purchased securities of Checkpoint between March 10, 2021 and December 15, 2023 (the "Class Period").

The Amended Complaint ("AC") claims violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b–5, the corresponding rule promulgated by the Securities and Exchange Commission ("SEC"). Dkt. 36. The AC's gravamen is that Checkpoint misled the market about its regulatory risk profile—centrally, its prospects of receiving approval from the U.S. Food and Drug Administration ("FDA") for marketing a novel skin cancer therapy, cosibelimab.

Pending now is defendants' motion to dismiss the AC under Federal Rule of Civil Procedure 12(b)(6). For the following reasons, the Court grants the motion and dismisses the AC in its entirety.

I. Background

A. Factual Background[1]

1. The Parties

Checkpoint, based in Waltham, Massachusetts, is a biopharmaceutical company that acquires, develops, and commercializes cancer treatments. AC ¶ 19. Since October 2015, Oliviero has served as Checkpoint's CEO and President. *Id.* ¶ 20.

Lead plaintiff Bailey acquired Checkpoint securities during the Class Period. *Id.* ¶ 17.

2. The FDA Approval Process for Biologics Drugs

Plaintiffs' claims center on defendants' statements about the FDA approval process for cosibelimab, which was Checkpoint's "lead product candidate" during the Class Period—that is, the furthest along in the development-to-commercialization pipeline. *Id.* ¶ 28. Cosibelimab is an antibody used in the treatment of locally advanced and metastatic cutaneous squamous cell carcinoma ("CSCC"), a form of skin cancer. *Id.*

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[1] These facts are drawn primarily from the AC. Dkt. 36. For the purpose of resolving the motion to dismiss, the Court assumes all well-pled facts to be true and draws all reasonable inferences in favor of plaintiffs. *See Koch v. Christie's Int'l PLC*, 699 F.3d 141, 145 (2d Cir. 2012). The Court has also considered the documents attached to the declaration of Brett D. Jaffe in support of the motion to dismiss, Dkt. 39 ("Jaffe Decl."), and the documents attached to the declaration of Garth Spencer in opposition to that motion, Dkt. 42 ("Spencer Decl."). Because these documents were incorporated into the AC by reference, or are matters of public record, they are properly considered on a motion to dismiss. *See City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 179 (2d Cir. 2014) (in resolving a motion to dismiss, the court may consider, *inter alia*, "any statements or documents incorporated in it by reference, as well as public disclosure documents required by law to be, and that have been, filed with the SEC, and documents that the plaintiffs either possessed or knew about and upon which they relied in bringing the suit"). The Court considered these documents "not for the truth of the matters asserted therein," but only "for the fact that the statements were made." *Clark v. Kitt*, No. 12 Civ. 8061, 2014 WL 4054284, at *7 (S.D.N.Y. Aug. 15, 2014); *see also, e.g.*, *Staehr v. Hartford Fin. Servs. Grp.*, 547 F.3d 406, 425 (2d Cir. 2008) ("[I]t is proper to take judicial notice of the fact that press coverage, prior lawsuits, or regulatory filings contained certain information, without regard to the truth of their contents." (emphasis omitted)).

Commercial distribution of a biologics drug like cosibelimab requires FDA approval.[2] That process involves several steps, which can be summarized as follows.

First, a company seeking to market a biologics drug—known as the "sponsor"—must submit a biologics license application ("BLA") to the FDA. 21 C.F.R. § 601.2. In support of the BLA, the sponsor must provide, *inter alia*, testing results, product development information, and descriptions of manufacturing processes. *Id.* ¶ 48.

Second, once the FDA accepts a BLA for review, the FDA assigns a "goal date" by which it will make a decision to approve or reject the BLA, approximately 12 months from submission, in accordance with the Prescription Drug User Fee Act of 1992 (the "PDUFA goal date"). *Id.* ¶ 49. The FDA holds a mid-cycle meeting with the company approximately five months after the BLA is filed, and a late-cycle meeting approximately four months later, in which it discusses any concerns that have emerged from its review of the BLA. *Id.*

Third and salient here, as part of its review process, the FDA may inspect the facility in which the drugs will be commercially manufactured. FDA inspectors evaluate the facility's compliance with Current Good Manufacturing Practices ("cGMP") regulations, assess readiness for commercial manufacturing, and authenticate the data submitted with the BLA. *Id.* ¶ 51. cGMPs require, *inter alia*, that a manufacturer assure "data integrity," including by putting in place "appropriate controls to assure that changes to computerized MPCRs [master production and control records] or other cGMP records or input of laboratory data into computerized records

[2] Biologics drugs are isolated from natural sources, in contrast to chemically synthesized drugs. *See, e.g.*, 21 C.F.R. § 600.3(h) ("Biological product means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.").

can be made only by authorized personnel." *Id.* ¶ 45. If inspectors observe potential noncompliance with cGMP regulations, the FDA may issue a "Form 483" to the manufacturing facility, noting these observations. *Id.* ¶¶ 5, 51.

After an inspection, the FDA assigns one of three designations: (1) "no action indicated," which signifies that inspectors did not find any objectionable conditions or practices; (2) "voluntary action indicated," which means that inspectors found objectionable conditions or practices, but are not prepared to take or recommend any regulatory action; or (3) "official action indicated" ("OAI"), which signifies that the inspected facility "is not considered to be in an acceptable state of compliance with regards to CGMP and may be subject to regulatory or enforcement action." *Id.* ¶ 89. An OAI designation "may result in non-approval of pending applications." *Id.*

At the end of the review process, if the FDA does not approve a BLA in its present form, it issues a Complete Response Letter ("CRL") to the sponsor, in which it explains the basis for its decision, and when possible, recommends steps to remediate any issues. 21 C.F.R. § 314.110(a).

3. Checkpoint Seeks FDA Approval to Market Cosibelimab

Checkpoint is a "small company," so it contracts with third parties to manufacture its products on a commercial scale. AC ¶ 2. On October 2, 2020, Checkpoint entered into an agreement with Samsung Biologics ("Samsung") under which Samsung was to commercially manufacture cosibelimab. *Id.* ¶ 4.

On January 3, 2023, Checkpoint announced that it had submitted a BLA to the FDA, seeking its approval to bring cosibelimab to market. *Id.* ¶ 8. The FDA accepted the BLA for review and set a PDUFA goal date of January 3, 2024, by which it would issue an initial decision approving or rejecting the BLA. *Id.* ¶ 131.

Between June 12 and 16, 2023, the FDA inspected Checkpoint's headquarters in Waltham. *Id.* ¶ 169. Although Oliviero was not present on the day the inspectors arrived, he attended the remaining four days of the inspection. *Id.*

On August 14, 2023, Checkpoint announced that its "midcycle communication meeting with the FDA was successfully completed." *Id.* ¶ 162.

Between August 21 and September 1, 2023, the FDA conducted a "pre-announced" inspection at Samsung that "covered multiple products," and "served as the preapproval inspection for Checkpoint's cosibelimab BLA, as well as the pre-approval inspection for Eli Lilly's lebrikizumab BLA." *Id.* ¶ 84. After the inspection, the FDA issued a Form 483 to Samsung, listing the FDA's "inspection observations." *Id.* The Form 483 bears the date September 1, 2023. *Id.*, Ex. 4. The observations in the Form 483 included that "the Manufacturing Scientific Analytical Technology (MSAT) laboratory used in support of application submission testing data had inadequate controls over data integrity" and "there [wa]s no means of determining with absolute certainty the true reliability of all test data." *Id.*[3] The Form 483 stated, however, that it "d[id] not represent a final agency determination regarding [] compliance." *Id.*

On October 12, 2023, the FDA inspectors issued an establishment inspection report to Samsung. *Id.*, Ex. 5 (the "EIR"). The EIR designated the inspection as "official action indicated," which, as noted, signifies that the facility "is not considered to be in an acceptable state of compliance with regards to CGMP and may be subject to regulatory or enforcement

[3] On October 2, 2023, Eli Lilly issued a press release announcing that the FDA had issued a CRL denying its BLA for lebrikizumab. As alleged, the CRL "cited findings that arose during a multi-sponsor inspection of a thirdparty, contract manufacturing organization that included the monoclonal antibody drug substance for Lilly's lebrikizumab."

action, and . . . may result in non-approval of pending applications." *Id.* ¶ 89. It recommended that the FDA withhold approval. *Id.*, Ex. 5.

On November 13, 2023, Checkpoint announced that Samsung "received certain observations from the FDA on Form 483 related to a recent multi-sponsor on-site inspection" that included cosibelimab. *Id.* ¶ 144.

On December 18, 2023, Checkpoint announced that the FDA had issued a CRL denying the cosibelimab BLA. It stated that "the only deficiencies" cited by the CRL "relate to the FDA's inspection of our third-party contract manufacturing organization [Samsung]," which "we believe we can address . . . in a resubmission to enable marketing approval in 2024." *Id.* ¶¶ 151–52. The CRL, Checkpoint stated, did not identify "any concerns about the clinical data package, safety, or labeling for the approvability of cosibelimab." *Id.*

After this announcement, Checkpoint's stock price fell $1.49 (44.9%) relative to the previous day's closing price. On April 5, 2024, a shareholder plaintiff filed this putative class action.

In December 2024, the FDA approved Checkpoint's re-submitted BLA for cosibelimab. *See* Dkt. 38 at 4 n.2 ("Pls' Br."); Dkt. 48 at 1 n.1 ("Defs.' Reply Br.").

4. Form 483s Previously Issued to Samsung

The AC alleges that, between 2016 to 2023, the FDA issued 10 Form 483s to Samsung, before it issued the Checkpoint-related Form 483 summarized above. *Id.* ¶ 7. The AC does not allege that any of the earlier Form 483s related to any Checkpoint products or that Samsung ever notified Checkpoint about them.[4] It does not identify the products or clients involved. It does

[4] For ease of exposition, the Court refers to these Form 483s as "non-Checkpoint Form 483s." The Court uses "Form 483" or "Checkpoint-related Form 483" to refer to the form issued on September 1, 2023 in connection with the FDA's multi-sponsor inspection of Samsung from August 21 to September 1, 2023, including as to cosibelimab.

not allege that each the non-Checkpoint Form 483s involved the same manufacturing facility as the Checkpoint Form 483. Nor does it allege that any of the non-Checkpoint Form 483s resulted in an OAI designation or the denial of a pending BLA—the fate suffered by the cosibelimab BLA. *Id.* ¶¶ 71–83.

The prior Form 483s issued to Samsung are as follows:

On June 22, 2016, the FDA issued a Form 483 that listed 15 observations, including that "[t]he firm's monitoring program and equipment did not detect breaches in HEPA filters," and that "[p]rocedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed." *Id.* ¶ 72.

On July 25, 2017, the FDA issued a Form 483 that listed four observations, including that "[l]aboratory controls used to release [redacted] drug substance do not include scientifically sound and appropriate test procedures that assure conformance to appropriate standards of quality and purity," and that "[d]eviation investigations are inadequate." *Id.* ¶ 73.

On March 14, 2018, the FDA issued a Form 483 that contained two observations: "QA oversight is in adequate [sic]" and "[p]est control alert limit and action limit are inadequate." *Id.* ¶ 74.

On May 11, 2018, the FDA issued a Form 483 that listed five observations, including that "[p]rocedures to prevent microbial contamination of drug products purporting to be sterile are not followed," and that "[t]he Quality Control Unit lacks authority to review production records to assure that no errors have occurred." *Id.* ¶ 75.

On June 26, 2018, the FDA issued a Form 483 containing three observations, including that "[e]mployees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions," and that "[e]quipment used in the manufacture,

processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use." *Id.* ¶ 76.

On September 10, 2019, the FDA issued a Form 483 that listed three observations including that "[u]tilities and Equipment are not adequately maintained," and that "[w]ritten procedures to ensure control over the transfer of QC materials is inadequate." *Id.* ¶ 77.

On November 1, 2019, the FDA issued a Form 483 containing one observation, that "[d]eviations from written production and process control procedures are not recorded and justified." *Id.* ¶ 78.

On August 24, 2021, the FDA issued a Form 483 that listed two observations: "Acceptance criteria for cleaning validation are not always justified to prevent product crosscontamination," and "[d]iscrepancies are not always investigated to identify the root cause to implement adequate corrective actions." *Id.* ¶ 79.

On June 9, 2022, the FDA issued a Form 483 that contained three observations, including that "[t]he endotoxin detection method is not reliable to detect endotoxin consistently in all the inprocess and release samples for [redacted]," and "[w]ritten procedures for cleaning and maintenance provide inadequate description of actions to be taken and/or not followed." *Id.* ¶ 80.

On February 28, 2023, the FDA issued a Form 483 that listed three observations, including that "[t]he responsibilities and procedures applicable to the quality control unit were not always fully followed," and more specifically that "deviations reported that the initial Quality Control Unit review of the referenced records did not identify data discrepancy, data handling, and calculation errors and follow-up investigations were not complete." *Id.* ¶ 81. The AC alleges that a June 1, 2023 report in a South Korean business news outlet called "SBS Biz"

regarding issues at Samsung's MSAT laboratory would have amplified the public salience of the February 28, 2023 Form 483. *Id.* ¶ 82; *see id.*, Ex. 6 ("SBS Biz news report"). As developed below, however, the AC is internally contradictory as to the events covered by the SBS Biz news report. The news report itself, annexed to the AC, contains no hint that it is related to an FDA inspection. *See id.*, Ex. 6.

B. Challenged Statements During the Class Period

The AC alleges that a number of public statements by Checkpoint and its CEO during the Class Period were knowingly false or misleading because they concealed the extent to which the FDA was likely to deny the cosibelimab BLA as a result of Samsung's regulatory compliance problems. The AC cites two categories of statements relating to Checkpoint's likelihood of obtaining regulatory approval to market cosibelimab (1) *before* the cosibelimab-related inspection of Samsung in late August 2023; and (2) *after* that inspection through the issuance of the CRL in December 2023.

As to the first category, the AC alleges that defendants' statements were misleading because they did not disclose that, since 2016, FDA inspections of Samsung had resulted in the issuance of 10 Form 483s. Although those Form 483s concerned products that Samsung was manufacturing for other clients, the AC alleges that defendants' omission of these Form 483s was misleading because these reflected on the overall regulatory risk faced by Checkpoint from its manufacturing relationship with Samsung. The statements in this category span the period between March 9, 2021 and March 31, 2023.

As to the second category, the AC alleges that defendants' statements were misleading because they (1) initially did not disclose that Samsung had received the Form 483 after the cosibelimab-related inspection, and (2) later inflated the likelihood that Samsung would timely address the issues identified in the Form 483, such that Checkpoint could win FDA approval of

the cosibelimab BLA by the PFUDA goal date of January 3, 2024. The statements in this category span the period between September 11 and November 13, 2023.

1. Statements Before the Late-August 2023 Inspection

The AC alleges that the following statements by Checkpoint and its CEO, Oliviero, were false and/or misleading, for failure to disclose that, since 2016, the FDA had issued Form 483s to Samsung in relation to products manufactured for clients other than Checkpoint.

March 9, 2021: On March 9, 2021, two years before the FDA's inspection of Samsung in relation to the cosibelimab BLA, Checkpoint announced that it had contracted with Samsung to manufacture cosibelimab. In a press release attached to a Form 8-K that Checkpoint filed with the SEC, it stated: "[I]n November 2020, Checkpoint announced the expansion of a long-term manufacturing partnership for cosibelimab with Samsung Biologics. Building upon an existing contract manufacturing agreement entered into in 2017, Samsung Biologics will provide additional commercial-scale drug substance manufacturing for cosibelimab." AC ¶ 106. It quoted Oliviero as stating, "We look forward to a transformative year as we continue our progress towards our first BLA submission with the U.S. Food and Drug Administration ('FDA') for cosibelimab in 2022." *Id.* ¶ 107. The AC alleges that these statements were misleading for failure to disclose that, between June 22, 2016 and March 9, 2021, seven FDA inspections of Samsung had resulted in the issuance of Form 483s.

March 12, 2021: On March 12, 2021, Checkpoint filed its annual report for 2020, in which it stated:

> As part of the approval process, the FDA must inspect and approve each manufacturing facility. Among the conditions of approval is the requirement that a manufacturer's quality control and manufacturing procedures conform to cGMP. Manufacturers must expend significant time, money and effort to ensure continued compliance, and the FDA conducts periodic inspections to certify compliance. It may be difficult for our manufacturers or us to comply with the applicable cGMP, as interpreted by the FDA, and other FDA regulatory requirements. If we, or our

> contract manufacturers, fail to comply, then the FDA may not allow us to market products that have been affected by the failure.

Id. ¶ 110. As to "supply and manufacturing," it stated:

> [W]e expect that we will rely on a single contract manufacturer to produce each of our product candidates under current GMP ("cGMP") regulations. . . . Contract manufacturers are subject to ongoing periodic and unannounced inspections by the FDA, the Drug Enforcement Administration ("DEA") and corresponding state agencies to ensure strict compliance with cGMP and other state and federal regulations. . . . We do not have control over third-party manufacturers' compliance with these regulations and standards, other than through contractual obligations. If they are deemed out of compliance with cGMPs, product recalls could result, inventory could be destroyed, production could be stopped, and supplies could be delayed or otherwise disrupted.

Id. ¶ 111. It also identified the following risk factors related to its use of third-party manufacturers:

> The facilities used by our third-party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA or BLA to the FDA. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third-party manufacturers, but we do not control the day-to-day manufacturing operations of, and are dependent on, our third-party manufacturers for compliance with cGMP regulations for manufacture of our product candidates. Third-party manufacturers may not be able to comply with the cGMP regulations or similar regulatory requirements outside the United States.
>
> Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, restrictions on imports and exports, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product and customer confidence in our product.

Id. ¶ 113. The AC alleges that these statements were misleading for failure to disclose that, between June 22, 2016 and March 12, 2021, seven FDA inspections of Samsung had resulted in the issuance of Form 483s.

January 25, 2022: On January 25, 2022, Checkpoint held a conference call to announce clinical trial results related to its development of cosibelimab. An analyst asked Oliviero: "What do you consider are the rate-limiting steps for the BLA? And I guess, any comments you could

talk about [sic] with regard to CMC and any issues with regard to supply chain?" Oliviero responded:

> Yeah. So any initial NDA or BLA for a company takes time to put together. We've been actually working on it for a number of months now for the sections we could put together, and with this data, we can now really hit the gas pedal on the additional sections. It does take time, and we want to put in a quality filing to have our best shot at a first cycle approval. I think there's a very good probability that we will be successful there, but we want to make sure it's right. So we've guided for a submission for later this year. There's no issues that we see that we can't overcome during the review, but until you go through it, you never know.
>
> As far as supply chain, we're lucky to have the largest contract manufacturer in the world of biologics as our partner, that's Samsung Biologics as our contract manufacturer for drug substance and drug product. They have incredible amounts of supply capacity there. Our current capacity allows us to get through initial launch, and then they still have additional capacity beyond that for us to continue to scale up for the potential increased sales, two, three, four, five years out from now, from initial launch. So, we're very happy to have Samsung behind us and we're in good shape.

Id. ¶ 117. The AC alleges that these statements were misleading for failure to disclose that, between June 22, 2016 and January 25, 2022, eight FDA inspections of Samsung had resulted in the issuance of Form 483s.

March 28, 2022: On March 28, 2022, Checkpoint filed its annual report for 2021. It contained the same statements from Checkpoint's 2020 annual report that the AC alleges were false and/or misleading. The AC alleges that these statements were misleading for failure to disclose that, between June 22, 2016 and March 28, 2022, eight FDA inspections of Samsung had resulted in the issuance of Form 483s.

August 12, 2022: On August 12, 2022, in a press release attached to its Form 8-K, Checkpoint stated:

> In July 2022, Checkpoint successfully completed two pre-BLA meetings with the FDA (chemistry, manufacturing and controls [CMC] and clinical/non-clinical). Based upon favorable interactions with the agency, the planned BLA submission will include both the metastatic and locally advanced indications. Checkpoint also

> reached agreement with the FDA on all key aspects discussed with regard to the content of the upcoming BLA submission.

Id. ¶ 122. It quoted Oliviero as stating, "Over the past few months, we have made substantial progress towards the regulatory submission for, and potential approval of, cosibelimab . . . Importantly, we successfully completed our pre-BLA meetings with the FDA in July, reaching agreement on all key aspects discussed with regard to the upcoming BLA submission." *Id.* ¶ 123. The AC alleges that these statements were misleading for failure to disclose that, between June 22, 2016 and August 12, 2022, nine FDA inspections of Samsung had resulted in the issuance of Form 483s.

January 18, 2023: On January 18, 2023, at B. Riley Securities' Third Annual Oncology Conference, in response to an analyst's question about "regulatory filing" and "the review process," Oliviero stated:

> This was again conducted to study under an IND so we had FDA buy-in since the beginning of the clinical development program and that's buy-in not just for the cutaneous squamous cell carcinoma study, you know, the design, the size the endpoints [sic], but also on the CMC program. We have the largest contract manufacturer in the world of biologics behind us manufacturing this, that's Samsung Biologics, and so having the FDA involved from the beginning, seeing the batches that we've run and the assays we've developed, and taking their input and applying it to our program, is extremely important and I think a wise decision on our part, so that we have a complete package and essentially what the FDA's expecting of us going into submitting that BLA earlier this month.

Id. ¶¶ 126–27. The AC alleges that these statements were misleading for failure to disclose that, between June 22, 2016 and January 16, 2023, nine FDA inspections of Samsung had resulted in the issuance of Form 483s.

March 30, 2023: On March 30, 2023, Checkpoint published a press release announcing its financial results for 2022, which stated:

> In July 2022, Checkpoint successfully completed two pre-BLA meetings with the FDA (chemistry, manufacturing and controls and clinical/non-clinical). Based upon

> favorable interactions with the agency, the January 2023 BLA submission included both the metastatic and locally advanced cSCC indications. Checkpoint also reached agreement with the FDA on all key aspects discussed regarding the content of the BLA submission. . . . [W]e began 2023 with the submission of our Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") seeking approval of cosibelimab. . . . Our BLA submission was subsequently accepted for filing and is under active review with a Prescription Drug User Fee Act ('PDUFA') goal date of January 3, 2024. . . . In its BLA filing acceptance letter, the FDA indicated that no potential filing review issues have been identified, and that an advisory committee meeting to discuss the application is not currently planned.

Id. ¶ 130. The AC alleges that these statements were misleading for failure to disclose that, between June 22, 2016 and March 30, 2023, 10 FDA inspections of Samsung had resulted in the issuance of Form 483s.

March 31, 2023: The next day, Checkpoint filed its annual report for 2022. It contained the same statements from Checkpoint's 2021 and 2020 annual reports that the AC alleges were false and/or misleading. The AC alleges that these statements were misleading for failure to disclose that, between June 22, 2016 and March 31, 2023, 10 FDA inspections of Samsung had resulted in the issuance of Form 483s.

2. Statements Made After the Inspection

The AC alleges that the following statements were misleading (1) for failure to disclose, until November 13, 2023, that Samsung had received a Form 483 on or about September 1, 2023; (2) after making this disclosure, for misrepresenting the likelihood that the FDA would deny the Cosibelimab BLA; and/or (3) for concealing the EIR's "official action indicated" designation and recommendation to withhold approval.

September 11, 2023: On September 11, 2023, at the H.C. Wainwright Investment Conference, Oliviero stated:

> So, with regard to the regulatory timeline, with regard to our BLA, again, we submitted in January, it was accepted for filing in March. That's when we learned that there was no advisory committee meeting planned by the FDA. We were

> assigned that PDUFA goal date of January of 2024. Most recently, we announced that we completed our mid-cycle communication meeting with the FDA, whereby the FDA communicated no significant review issues and no safety concerns identified to date, so doing very well towards our approval. The late-cycle meeting is now scheduled for late October, and we look forward to moving through the rest of the process and having a successful PDUFA goal date in January.

Id. ¶ 137. The AC alleges that these statements were misleading for failure to disclose that, between June 22, 2016 and September 11, 2023, 11 FDA inspections of Samsung had resulted in the issuance of Form 483s, including the Form 483 issued in relation to cosibelimab.

September 28, 2023: On September 28, 2023, at the Cantor Global Healthcare Conference, an analyst asked Oliverio: "[T]he PDUFA date [is] coming up in just a couple of months. Maybe recap the kinds of discussions you've had with the FDA and communications and what steps are left between now and that date." *Id.* ¶ 140. Oliviero responded:

> So it was a very typical process for a full BLA review. We filed or submitted the BLA back in January of this year 2023. It was accepted for filing, which is when we found out that the FDA was not planning an advisory committee meeting. We then progressed through the review. Again a very typical review. Most recently, we had our mid-cycle meeting with the FDA, whereby they conveyed to us that there were no significant issues, no safety concerns thus far with the BLA review, so very clean bill of health as of that point in time with the FDA. And now we've entered into the labeling discussion, part of the BLA process, so it's moving forward very nicely, and we're looking forward to hearing the results very soon.

Id. ¶ 141. The AC alleges that these statements were misleading for failure to disclose that, between June 22, 2016 and September 28, 2023, 11 FDA inspections of Samsung had resulted in the issuance of Form 483s, including the Form 483 issued in relation to cosibelimab.

November 13, 2023: On November 13, 2023, Checkpoint filed its Form 10-Q with the SEC, in which it stated:

> Our contract manufacturer for cosibelimab has received certain observations from the FDA on Form 483 related to a recent multi-sponsor on-site inspection. While we believe the manufacturer will adequately respond to and address the observations during our BLA review timeline, there is no guarantee that the FDA will agree with the response and remediations in a timely manner or at all, which

> could negatively impact our ability to obtain regulatory approval for cosibelimab or obtain approval within projected timelines.

Id. ¶ 144. It issued a press release that same day. *Id.* ¶ 146–48. The AC alleges that these statements were misleading for failure to adequately disclose that, between June 22, 2016 and September 28, 2023, 11 FDA inspections of Samsung had resulted in the issuance of Form 483s, including the Form 483 issued in relation to cosibelimab. These statements were also misleading, the AC alleges, because they did not disclose the existence of the EIR and that the FDA had already rejected Eli Lilly's lebrikizumab BLA.

C. Oliviero's Compensation and Trading Activity

The AC alleges that CEO Oliviero's incentive-based compensation during the Class Period gave him a motive to artificially inflate its stock price and that his stock sales during that period reflect his awareness of Samsung's undisclosed problems.

As alleged, a portion of Oliviero's compensation came in the form of stock awards issued under Checkpoint's Amended and Restated 2015 Incentive Plan. *Id.* ¶¶ 179–81. Oliviero was awarded $1,417,570, $1,151,150, and $720,000 in Checkpoint stock for 2021, 2022, and 2023, respectively. *Id.* ¶ 179.[5] The AC alleges that Oliviero's stock awards were based on performance goals that "may" have included metrics such as "stock price or performance," "total shareholder return," "market capitalization," and "corporate financing activities." *Id.* ¶ 181 (capitalization altered).

The AC alleges that, between 2016 and the start of the Class Period, Oliviero had sold Checkpoint stock only to satisfy tax-withholding obligations that arose when his stock awards vested under the Incentive Plan. *Id.* ¶ 172. However, it alleges, between April 4 and June 23,

[5] As alleged, Oliviero's total annual compensation from Checkpoint was $2,292,370, $2,042,150, and $1,641,591, for 2021, 2022, and 2023, respectively. *Id.* ¶ 179.

2022, Oliviero sold 397,641 Checkpoint shares in seven separate transactions that were *not* undertaken to satisfy tax-withholding obligations, *id.* ¶ 173; these generated total proceeds of $512,644.55. By far the most substantial of these was on June 17, 2022, when Oliviero sold 228,000 shares for $248,520. *Id.*

The AC also alleges that, during the Class Period, Oliviero transferred Checkpoint stock to an irrevocable trust held for the benefit of his minor children. *Id.* ¶ 175. He transferred Checkpoint stock worth $589,800 on September 26, 2022; Checkpoint stock worth $182,700 on February 24, 2023; and Checkpoint stock worth $18,890.10 on August 16, 2023. *Id.*

D. Procedural History

On April 5, 2024, plaintiff James Moore filed this putative securities class action on behalf of all individuals who purchased shares of Checkpoint between March 10, 2021 and December 15, 2023. Dkt. 1 ("Compl.") ¶ 1. That same day, notice of this action was published in News Wire. Dkt. 8, Ex. 1. As required by the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4(a)(3)(A), the notice summarized the basis for this action and informed members of the putative class that they had 60 days to move for appointment as lead plaintiff. That 60-day period expired on June 4, 2024.

On June 21, 2024, the Court granted an unopposed motion by plaintiff Hamilton Bailey to be appointed lead plaintiff and to have his attorneys, Glancy Prongay & Murray LLP, be appointed lead counsel. Dkt. 31. On June 27, 2024, the Court set a schedule for the filing of an amended complaint and briefing of defendants' anticipated motion to dismiss. Dkt. 33.

On August 23, 2024, Bailey filed the operative AC, Dkt. 36, to which he annexed a declaration by Jennifer Ahearn, Dkt. 36, Ex. 3 ("Ahearn Decl."). On October 23, 2024, defendants moved to dismiss, Dkt. 37, and filed a memorandum of law in support, Dkt. 38

("Defs.' Br.").[6] On December 23, 2024, forgoing the opportunity provided by the Court in its scheduling order to file a Second Amended Complaint, plaintiffs opposed defendants' motion. Dkt. 38. On February 3, 2025, defendants filed a reply. Dkt. 43.

II. Applicable Legal Standards

A. Motions to Dismiss

To survive a motion to dismiss under Rule 12(b)(6), a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim will only have "facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A complaint is properly dismissed where, as a matter of law, "the allegations in a complaint, however true, could not raise a claim of entitlement to relief." *Twombly*, 550 U.S. at 558. Although the Court must accept as true all well-pled factual allegations in the complaint and draw all reasonable inferences in the plaintiff's favor, *Steginsky v. Xcelera Inc.*, 741 F.3d 365, 368 (2d Cir. 2014), that tenet "is inapplicable to legal conclusions," *Iqbal*, 556 U.S. at 678.

"Securities fraud claims are subject to heightened pleading requirements that the plaintiff must meet to survive a motion to dismiss." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 321–23 (2007).

First, a complaint alleging securities fraud must meet the requirements of Federal Rule of Civil Procedure 9(b). *See ECA & Local 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009) ("*ECA*"). Rule 9(b) states that "[i]n alleging fraud

[6] Defendants also moved to strike the Ahearn Declaration, under Federal Rule of Civil Procedure 10(c), as improperly appended to the Complaint.

or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "Allegations that are conclusory or unsupported by factual assertions are insufficient." *ATSI Commc'ns*, 493 F.3d at 99.

Second, the PSLRA imposes "[e]xacting pleading requirements" on plaintiffs asserting securities fraud claims. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007) (citing 15 U.S.C. § 78u-4(b)). In particular, where a plaintiff's claims depend upon allegations that the defendant has made an untrue statement of material fact or that the defendant omitted a material fact necessary to make a statement not misleading, the plaintiff "shall specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1). Thus, to plead a claim of securities fraud, plaintiffs "must do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004). In addition, a plaintiff must, "with respect to each act or omission . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2).

B. Elements of the AC's Claims

The AC brings claims under §§ 10(b) and 20(a) of the Exchange Act, and Rule 10b-5. AC ¶¶ 199–213.

Section 10(b) of the Exchange Act makes it unlawful to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." 15 U.S.C. § 78j(b). The SEC's implementing rule, Rule 10b-5, provides that it is unlawful "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make

the statements made, in light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b).

To state a claim under § 10(b) of the Exchange Act, a complaint must adequately plead "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37–38 (2011) (citation omitted). A complaint must ultimately allege conduct involving manipulation or deception; § 10(b) does not cover "instances of corporate mismanagement . . . in which the essence of the complaint is that shareholders were treated unfairly by a fiduciary." *Santa Fe Indus., Inc. v. Green*, 430 U.S. 462, 477 (1977).

Section 20 extends liability to persons who "control" entities alleged to have violated Section 10. To state a claim under § 20(a) of the Exchange Act, "a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." *Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 236 (2d Cir. 2014) (quoting *ATSI Commc'ns*, 493 F.3d at 108). If a plaintiff has not adequately alleged a primary violation—that is, a viable claim under another provision of the Exchange Act—then the § 20(a) claims must be dismissed. *See id.*

III. Discussion

Defendants mount two principal challenges to the AC. First, they argue that it does not adequately allege falsity. Second, they argue that it fails to raise a strong inference of scienter.

Defendants are correct on each point.[7] For these two independent reasons, the AC does not meet the "[e]xacting pleading requirements" of the PSLRA, *Tellabs*, 551 U.S. at 313. The Court therefore grants defendants' motion to dismiss.

A. Falsity

1. Applicable Law

a. False or Misleading Statements or Omissions

To survive a motion to dismiss, a complaint must adequately plead "that the defendant made a statement that was 'misleading as to a material fact.'" *Matrixx Initiatives*, 563 U.S. at 38 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988) (emphasis omitted)). Significantly, § 10(b) and Rule 10b–5 "do not create an affirmative duty to disclose any and all material information." *Id.* at 44; *see also Basic*, 485 U.S. at 239 n.17. "Disclosure of . . . information is not required . . . simply because it may be relevant or of interest to a reasonable investor." *Resnik v. Swartz*, 303 F.3d 147, 154 (2d Cir. 2002). An omission of information not affirmatively required to be disclosed is, instead, actionable only when disclosure of such information is "necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx Initiatives*, 563 U.S. at 44 (quoting 17 C.F.R. § 240.10b–5(b)); *see also Macquarie Infrastructure Corp. v. Moab Partners, L.P.*, 601 U.S. 257, 264 (2024).

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[7] Defendants separately move to dismiss based on a challenge to the AC's allegations as to loss causation. *See* Defs.' Br. at 20. They argue that the AC's theory of loss causation—that an undisclosed risk materialized, causing losses to investors—fails because Checkpoint had "expressly warned investors of the risk that materialized: the FDA's initial rejection of the cosibelimab BLA because of a Form 483." *Id.* at 2; *see Stratte-McClure v. Morgan Stanley*, 598 F. App'x 25, 29 (2d Cir. 2015) ("To allege a corrective disclosure, a plaintiff must allege that the disclosure revealed to the market the falsity of the prior statement."); *In re New Energy Sys. Sec. Litig.*, 66 F. Supp. 3d 401, 406 (S.D.N.Y. 2014). Because the AC's pleadings as to falsity and scienter are deficient, the Court has not had occasion to reach this argument.

The materiality requirement, meanwhile, "is satisfied when there is 'a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available.'" *Id.* at 38 (quoting *Basic*, 485 U.S. at 231–32). As the Supreme Court has explained, a lower standard—such as defining a "material fact" as any "fact which a reasonable shareholder might consider important"—would lead corporations to "bury the shareholders in an avalanche of trivial information[,] a result that is hardly conducive to informed decisionmaking." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448–49 (1976). The "materiality hurdle" is, therefore, "a meaningful pleading obstacle." *In re ProShares Trust Sec. Litig.*, 728 F.3d 96, 102 (2d Cir. 2013). However, because of the fact-intensive nature of the materiality inquiry, the Court may not dismiss a complaint "on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." *ECA, Loc. 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 197 (2d Cir. 2009) (quotation marks omitted).

b. Statements of Opinion

Like objective statements of material fact, subjective statements of opinion can be actionable as fraud. Such statements of opinion can give rise to liability in two distinct ways.

First, "liability for making a false statement of opinion may lie if either 'the speaker did not hold the belief she professed' or 'the supporting facts she supplied were untrue.'" *Tongue v. Sanofi*, 816 F.3d 199, 210 (2d Cir. 2016) (quoting *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 185 (2015)). "It is not sufficient for these purposes to allege that an opinion was unreasonable, irrational, excessively optimistic, [or] not borne out by subsequent events." *In re Salomon Analyst Level 3 Litig.*, 350 F. Supp. 2d 477, 489

(S.D.N.Y. 2004). "The Second Circuit has firmly rejected this 'fraud by hindsight' approach." *Podany v. Robertson Stephens, Inc.*, 318 F. Supp. 2d 146, 156 (S.D.N.Y. 2004) (citing *Stevelman v. Alias Research, Inc.*, 174 F.3d 79, 85 (2d Cir. 1999)).

Second, "opinions, though sincerely held and otherwise true as a matter of fact, may nonetheless be actionable if the speaker omits information whose omission makes the statement misleading to a reasonable investor." *Sanofi*, 816 F.3d at 210 (citing *Omnicare*, 575 U.S at 194). To adequately allege that a statement of opinion was misleading through the omission of material information, "[t]he investor must identify particular (and material) facts going to the basis for the issuer's opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context." *Id.* at 209 (quoting *Omnicare*, 575 U.S at 194). As the Second Circuit has explained, "a reasonable investor, upon hearing a statement of opinion from an issuer, 'expects not just that the issuer believes the opinion (however irrationally), but that it fairly aligns with the information in the issuer's possession at a time.'" *Id.* at 210 (quoting *Omnicare*, 575 U.S at 189). "The core inquiry," then, "is whether the omitted facts would 'conflict with what a reasonable investor would take from the statement itself.'" *Id.* (quoting *Omnicare*, 575 U.S at 189).

The Supreme Court has instructed that this second theory of liability for opinions, based on omissions of material facts that may render a statement of opinion actionable, should not be given "an overly expansive reading"; rather, establishing liability on such a theory "is no small task for an investor." *Id.* (quoting *Omnicare*, 575 U.S at 194). "Reasonable investors understand that opinions sometimes rest on a weighing of competing facts, . . . [and do] not expect that every fact known to an issuer supports its opinion statement." *Id.* (quoting *Omnicare*,

575 U.S at 189–90). "[A] statement of opinion 'is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way.'" *Id.* (quoting *Omnicare*, 575 U.S at 189).

c. The PSLRA Safe Harbor for Forward-Looking Statements

The PSLRA amended the Exchange Act to provide a safe harbor for forward-looking statements. *See* 15 U.S.C. § 78u–5(c). Forward-looking statements are defined as those that contain, among other things, "a projection of revenues, income, [or] earnings," "plans and objectives of management for future operations," or "a statement of future economic performance." *Id.* § 78u–5(i)(1). A forward-looking statement is not actionable if it "is identified and accompanied by meaningful cautionary language or is immaterial or the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading." *Slayton v. Am. Exp. Co.*, 604 F.3d 758, 766 (2d Cir. 2010). Because the statute is written in the disjunctive, statements are protected by the safe harbor if they fit any one of these three categories. *Id.* Materiality is defined above; the other two categories are defined as follows:

Meaningful cautionary language. To qualify as "meaningful," cautionary language "must convey substantive information about factors that realistically could cause results to differ materially from those projected in the forward-looking statements." *Id.* at 771 (quoting H.R. Conf. Rep. 104–369, at 43 (1995)). Language that is "vague" or "mere boilerplate" does not suffice. *Id.* at 772. "To determine whether cautionary language is meaningful, courts must first 'identify the allegedly undisclosed risk' and then 'read the allegedly fraudulent materials—including the cautionary language—to determine if a reasonable investor could have been misled into thinking that the risk that materialized and resulted in his loss did not actually exist.'" *In re Delcath Sys., Inc. Sec. Litig*, 36 F. Supp. 3d 320, 333 (S.D.N.Y. 2014) (quoting *Halperin v. eBanker USA.com, Inc.*, 295 F.3d 352, 359 (2d Cir. 2002)). Plaintiffs may establish that

cautionary language is not meaningful "by showing, for example, that the cautionary language did not expressly warn of or did not directly relate to the risk that brought about plaintiffs' loss." *Halperin*, 295 F.3d at 359.

Actual knowledge. The scienter requirement for forward-looking statements—actual knowledge—is "stricter than for statements of current fact. Whereas liability for the latter requires a showing of either knowing falsity or recklessness, liability for the former attaches only upon proof of knowing falsity," *Slayton*, 604 F.3d at 773 (quoting *Inst. Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 274 (3d Cir. 2009)), pled with the required particularity, *see* 15 U.S.C. § 78u–4(b)(2).

2. Application

The vast majority of the challenged statements constitute puffery, statements of opinion, and/or forward-looking statements that cannot serve as the basis of a federal securities claim. As to the few remaining statements that purport to relate historical information, the AC does not adequately allege that, in context, they were false or misleading.

a. Puffery

Statements are mere puffery, and hence non-actionable, when they are "too general to cause a reasonable investor to rely upon them," *ECA*, 553 F.3d at 206; *accord Kleinman v. Elan Corp.*, 706 F.3d 145, 153 (2d Cir. 2013); *Boca Raton Firefighters & Police Pension Fund v. Bahash*, 506 F. App'x 32, 37 (2d Cir. 2012).

A number of the statements challenged by the AC clearly fit into this category. These include that: Checkpoint was "look[ing] forward to a transformative year" in 2021, AC ¶ 107; it aimed to have the "best shot" at FDA approval, *id.* ¶ 117; it was "lucky" to be working with Samsung, *id.*; it was making "substantial progress" towards submitting the cosibelimab BLA, *id.* ¶ 123; having "FDA buy-in" was "important" to its anticipated BLA, *id.* ¶ 127; Checkpoint's

pre-submission strategy was "wise" and enhanced its preparedness, *id.*; and it planned to include "essentially what the FDA's expecting" in the cosibelimab BLA, *id.* Made more than two years before the FDA's inspection of Samsung for the cosibelimab BLA, these assertions expressed confidence as to Checkpoint's progress toward *submitting* the BLA. Insofar as these vague statements signaled the company's optimism as to the FDA's consideration of the BLA, they do no more than place a "positive spin on developments in the [FDA approval] process." *In re EDAP TMS S.A. Sec. Litig.*, No. 14 Civ. 6069, 2015 WL 5326166, at *9–10 (S.D.N.Y. Sept. 14, 2015).

Courts have widely held such statements "mere puffery" and therefore not actionable as securities fraud. *In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 757 (S.D.N.Y. 2018); *see In re EDAP*, 2015 WL 5326166, at *9–10 (statements "indicat[ing] that the [FDA approval] process was 'on track' and making continued 'progress,'" or "declar[ing] defendants' belief that they were 'moving through the approval process in a timely manner,'" "constitute inactionable puffery"); *Rombach,* 355 F.3d at 174 ("Up to a point, companies must be permitted to operate with a hopeful outlook: 'People in charge of an enterprise are not required to take a gloomy, fearful or defeatist view of the future; subject to what current data indicates, they can be expected to be confident about their stewardship and the prospects of the business that they manage.'" (quoting *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129–30 (2d Cir. 1994)); *see also, e.g.*, *Lasker v. N.Y. State Elec. & Gas Corp.*, 85 F.3d 55, 59 (2d Cir. 1996) (statement that company's "business strategies would lead to continued prosperity" constituted "precisely the type of 'puffery' that [the Second Circuit] and other circuits have consistently held to be inactionable."); *In re EDAP*, 2015 WL 5326166, at *4–5, *9–10 (statement that FDA's acceptance of a company's application was a "major milestone" was puffery); *Helo v. Sema4*

Holdings Corp., No. 22 Civ. 1131, 2024 WL 3593677, at *9 (D. Conn. July 31, 2024) (statements that "2021 was a transformative year," "Company [wa]s 'super pleased with the health systems partnerships we formed today,'" and "we're off to a strong start" were puffery); *City of Sterling Heights Gen. Emps.' Ret. Sys. v. Hospira, Inc.*, No. 11 Civ. 8332, 2013 WL 566805, at *24 (N.D. Ill. Feb. 13, 2013) (statement that company's new project would "transform" its operations was puffery); *Schaffer v. Horizon Pharma PLC*, No. 16 Civ. 1763, 2018 WL 481883, at *9 (S.D.N.Y. Jan. 18, 2018) (statement that company was "on track" was puffery); *In re XM Satellite Radio Holdings Sec. Litig.*, 479 F. Supp. 2d 165, 179–80 (D.D.C. 2007) (statements about "smart" and "sound" business model were puffery).

b. Opinion Statements and Forward-Looking Statements

Statements of opinion "include subjective statements that reflect judgments as to values that [are] not objectively determinable." *In re Gen. Elec. Co. Sec. Litig.*, 856 F. Supp. 2d 645, 653 (S.D.N.Y. 2012). Statements that "express expectations about the future rather than presently existing, objective facts" are also statements of opinion. *Fialkov v. Alcobra Ltd.*, No. 14 Civ. 9906, 2016 WL 1276455, at *6 (S.D.N.Y. Mar. 30, 2016). Such statements, often marked by phrases such as "I believe," are inactionable so long as the speaker actually held the belief professed, did not supply an untrue supporting fact, and did not omit information rendering the statement misleading. *See Omnicare*, 575 U.S at 183–84. Forward-looking statements, meanwhile, include "plans and objectives of management for future operations." 15 U.S.C. § 78u–5(i)(1). A forward-looking statement is not actionable if it "is identified and accompanied by meaningful cautionary language or is immaterial or the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading." *Slayton*, 604 F.3d at 766.

The vast majority of defendants' challenged statements as to their expectations regarding FDA approval and the timeline for cosibelimab's commercial release qualify as opinions,

forward-looking statements, or both. They express defendants' expectations for the future rather than representations as to extant, objective facts. And they were hardly categorical. Defendants consistently represented not that the FDA would necessarily approve the cosibelimab BLA but rather that they wished to put in their "best shot at a first cycle approval" and they believed there to be a "good probability" of "success[]"; they cautioned, too, that "until you go through [the FDA BLA process], you never know." AC ¶ 117; *see also, e.g.*, *id.* ("They still have additional capacity beyond that for us to continue to scale up for the potential increased sales, two, three, four, five years out from now, from initial launch."); *id.* ¶137 ("We look forward to moving through the rest of the process and having a successful PDUFA goal date in January."); *id.* ¶ 144 ("While we *believe* the manufacturer will adequately respond to and address the observations during our BLA review timeline, there is no guarantee that the FDA will agree with the response and remediations in a timely manner or at all, which could negatively impact our ability to obtain regulatory approval for cosibelimab or obtain approval within projected timelines." (emphasis added)).

Courts have commonly found an issuer's public statements to the effect that it felt "good" or "confident" about the FDA approval process non-actionable opinion statements. *Aramic LLC v. Revance Therapeutics, Inc.*, No. 21 Civ. 9585, 2024 WL 1354503, at *6–8 (N.D. Cal. Mar. 30, 2024); *see also, e.g.*, *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 535 (S.D.N.Y. 2015) ("The six statements about FDA approval are classically forward-looking—they address what defendants expected to occur in the future."), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016); *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 585 (S.D.N.Y. 2016) (statements about the FDA approval process "[we]re classically forward-looking, as they address[ed] what defendants expected to occur in the future"); *Kovtun v. VIVUS, Inc.*, No. 10 Civ. 4957, 2012 WL 4477647,

at *12 (N.D. Cal. Sept. 27, 2012) ("Projections about the likelihood of FDA approval are forward-looking statements.").

And from the start of the Class Period, Checkpoint's forward-looking statements were accompanied by a range of cautionary statements and/or further qualifying information. Defendants repeatedly warned that (1) Checkpoint was dependent on third-party manufacturers, (2) third-party manufacturers' practices require FDA approval, and (3) the failure of a third-party manufacturer to comply with FDA regulations could impede Checkpoint's ability to bring cosibelimab to market. The risk that ultimately materialized—the FDA's denial of the BLA due to a Samsung's noncompliance with cGMP—was encompassed by defendants' cautionary disclosures:

> Among the conditions of [FDA] approval is the requirement that a manufacturer's quality control and manufacturing procedures conform to cGMP. . . . It may be difficult for our manufacturers or us to comply with the applicable cGMP, as interpreted by the FDA, and other FDA regulatory requirements. If we, or our contract manufacturers, fail to comply, *then the FDA may not allow us to market products that have been affected by the failure.*

AC ¶ 110 (emphasis added).

Likewise, defendants, in expressing optimism that Samsung would be able to address the observations noted in the Form 483 issued September 2023, cautioned that "there [wa]s no guarantee that the FDA will agree with the response and remediations in a timely manner or at all, which could negatively impact our ability to obtain regulatory approval for cosibelimab or obtain approval within projected timelines." *Id.* ¶ 144. The AC's allegations thus reveal that defendants, far from concealing the risks, affirmatively disclosed the potential regulatory obstacle arising from Samsung's alleged non-compliance with cGMP regulations. And they unambiguously conveyed that this could delay Checkpoint's efforts to bring cosibelimab to market.

Resisting this conclusion, plaintiffs argue that defendants' statements, although framed as opinions or forward-looking statements, contained embedded assertions of fact that defendants knew to be false. Specifically, plaintiffs contend that even as defendants expressed optimism about the prospects of receiving FDA approval for marketing cosibelimab, they secretly knew, but failed to disclose, that Samsung had received the non-Checkpoint Form 483s, which would materially impede approval of the cosibelimab BLA.

This argument fails for two independent reasons.

First, the AC does not contain any non-conclusory allegations supporting that defendants actually knew of the allegedly omitted information at the time of the alleged misstatements. To begin with, the AC does not suggest that the FDA ever issued any of the allegedly omitted Form 483s to Checkpoint. Rather, as alleged, these were issued to third-party manufacturer Samsung. And 10 of the 11 Form 483s involved biologics drugs that Samsung was manufacturing for its clients *other than* Checkpoint. As developed in greater detail in connection with the discussion below of scienter, the AC is devoid of concrete allegations that Checkpoint or Oliviero were ever notified by Samsung about any of the non-Checkpoint Form 483s, much less that Checkpoint was privy to their contents before it made the statements the AC challenges as misleading. Any claim of an actionable opinion statement based on the non-Checkpoint Form 483s therefore necessarily founders. Nor does the AC allege that Samsung had notified Checkpoint of the Checkpoint-related Form 483 by the time Oliviero opined, in September 2023, that Checkpoint was "doing very well towards [FDA approval]," *id.* ¶ 137, and "moving forward very nicely," *id.* ¶ 141. Finally, the AC does not allege that defendants ever received the EIR that allegedly made Checkpoint's November 2023 opinion statement misleading. As a result, the AC does not supply a concrete basis to conclude that defendants did not genuinely believe the challenged

opinion statements at the time they made them, or that their forward-looking statements were knowingly false. *See Slayton*, 604 F.3d at 773.

Second, the AC does not adequately allege that defendants' opinion statements did not "fairly align[ ] with the information in [their] possession at the time," *Omnicare*, 575 U.S. at 189. The Supreme Court has instructed courts to evaluate opinion statements in context because "the investor takes into account the customs and practices of the relevant industry," and "an omission that renders misleading a statement of opinion when viewed in a vacuum may not do so once that statement is considered, as is appropriate, in a broader frame." *Id.* at 190. Here, the Form 483s that the AC alleges defendants failed to take into account —even assuming, incorrectly, it were well-pled that defendants knew of them—"[we]re merely observational in nature, and d[id] not represent the FDA's final word." *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 42 (1st Cir. 2014). The "advisory language" of a Form 483 indicates that "it lists only inspectional observations and do[es] not represent a final agency determination regarding [] compliance." *Id.* at 35; *see* AC, Ex. 4, at 1 (same). The AC notably does not plead that these issuances are final in practice. *See id.* ¶¶ 5, 51; *accord Schaeffer v. Nabriva Therapeutics plc,* No. 19 Civ. 4183, 2020 WL 7701463, at *2 (S.D.N.Y. Apr. 28, 2020); *In re Sanofi*, 87 F. Supp. 3d at 541–42 (S.D.N.Y. 2015); *Pub. Pension Fund Gr. v. KV Pharm. Co.*, 679 F.3d 972, 982–83 (8th Cir. 2012). Nor does it allege that *any* non-Checkpoint Form 483s resulted in the denial of a BLA or even an OIA designation triggering regulatory action. *See* AC ¶¶ 71–81 (listing "observations"); *see, e.g.*, *KV Pharm*, 679 F.3d at 982 (issuance of Form 483 presents possibility that "the FDA *may* take corrective action against a company" (emphasis added)). Simply put, the existence of the non-Checkpoint Form 483s, without more, does not support a plausible inference that defendants did not believe their generally positive forecasts of eventual regulatory approval. "Allegations . .

. 'that defendants should have anticipated future events and made certain disclosures earlier than they actually did do not suffice to make out a claim of securities fraud.'" *In re Express Scripts Holdings Co. Sec. Litig.*, 773 F. App'x 9, 15 (2d Cir. 2019) (quoting *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000)).

For similar reasons, the September 2023 opinion statements are not actionable. Plaintiffs fault these for not mentioning the Checkpoint-related Form 483. But even assuming Checkpoint learned of the Form 483 shortly after its issuance on September 1, 2023, it and CEO Oliviero did did not have a freestanding legal duty to disclose that event. *See, e.g.*, *Schaeffer*, 2020 WL 7701463, at *9 ("Because a Form 483 is interim FDA feedback, there is no standalone duty to disclose its existence."); *In re Genzyme*, 754 F.3d at 41–42 (same); *In re Sanofi*, 87 F. Supp. 3d at 541–42 (similar); *see also, e.g.*, *Matrixx Initiatives*, 563 U.S. at 44 ("[I]t bears emphasis that § 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information."); *Basic*, 485 U.S., at 239, n. 17 ("Silence, absent a duty to disclose, is not misleading under Rule 10b–5"). *In re Genzyme* is particularly apposite. There, the First Circuit held that a pharmaceutical company did not have an affirmative duty to disclose a Form 483 "at the time it was issued." 754 F.3d at 41–42. The FDA had issued this form, which noted potential cGMP violations, directly to the company, after an inspection of its manufacturing plant. *See id.* at 35. "[I]f there ever was" a duty to disclose the form, the court held, it arose four months later, only after certain developments "crystalized the relevance of the . . . Form 483 to defendants' earlier positive statements regarding [the BLA's] approval." *Id.* at 41–42. That logic applies *a fortiori* here, because, as alleged, Checkpoint was not the entity whose facility was inspected; the facility was used by multiple pharmaceutical companies for manufacturing multiple products; and the FDA issued the Form 483 to Samsung, rather than Checkpoint. And it

is only in hindsight—with awareness that the FDA ultimately did not approve cosibelimab by its January 3, 2024 PDUFA goal date—that the Form 483 presents as a formidable problem. As of September 2023, the PDUFA goal date for cosibelimab was more than three months away, the FAC is devoid of any factual allegation that the FDA approval process otherwise had encountered any hiccup, and the Form 483 related to multiple products at the Samsung facility, as opposed to speaking to an issue endemic to cosibelimab.

Viewed in this context, Oliviero's opinion statements—made in response to analysts' questions about Checkpoint's communications with the FDA—that the approval process was progressing "very well" and "nicely" are not actionable for failure to mention the Form 483. The AC does not articulate factually why Samsung would have been unable as of then to remedy the "observations" noted in that form in time for Checkpoint to meet the January goal. Nor does it plead factually why Checkpoint and Oliviero could reasonably only have expected such a miss. Thus, had Oliviero known of the Form 483 at the time of the September 2023 statements—and the AC notably does not allege this—the shortcomings reflected therein could reasonably have seemed "eminently correctable" by the PDUFA goal date. *Schaeffer*, 2020 WL 7701463, at *10; *see In re Discovery Lab'ys Sec. Litig.*, No. 06-1820, 2007 WL 789432, at *4 (E.D. Pa. Mar. 15, 2007) (similar), *aff'd*, 276 F. App'x 154 (3d Cir. 2008); *McClain v. Iradimed Corp.*, 111 F. Supp. 3d 1293, 1304–05 (S.D. Fla. 2015) (similar). The FDA, after all, at the mid-cycle meeting, had communicated that timely BLA approval was possible, and it had not since told Checkpoint otherwise.

"There is no inconsistency between a pharmaceutical company executive's concern about adverse events and the possibility of a negative FDA reaction to a proposed drug, and his sincere optimism that the FDA was likely to approve the drug." *In re Sanofi*, 87 F. Supp. 3d at 542.

That the Form 483 "was not disclosed at an earlier time that plaintiffs would have preferred, does not amount to a breach of the duty to disclose, if there ever was one." *In re Genzyme,* 754 F.3d at 42; *see, e.g.*, *Resnik v. Swartz*, 303 F.3d 147, 154 (2d Cir. 2002) ("Disclosure of an item of information is not required . . . simply because it may be relevant or of interest to a reasonable investor."). The AC's allegations do not support the inference that Oliviero's positive assessment of the FDA approval process conflicted with facts he then knew. And reasonable investors would not understand that assessment to mean no potential stumbling blocks existed. Such investors "understand that opinions sometimes rest on a weighing of competing facts." *Omnicare*, 575 U.S. at 190.

c. The Remaining Challenged Statements

The foregoing discussion inters the substantial majority of challenged statements in the AC as inactionable puffery, opinion statements, and forward-looking statements. But several challenged statements do purport to relate to historical facts. These include the following:

- "[I]n November 2020, Checkpoint announced the expansion of a long-term manufacturing partnership for cosibelimab with Samsung Biologics. Building upon an existing contract manufacturing agreement entered into in 2017, Samsung Biologics will provide additional commercial-scale drug substance manufacturing for cosibelimab." AC ¶ 106.

- "We've been actually working on [the cosibelimab BLA] for a number of months now for the sections we could put together, and with this data, we can now really hit the gas pedal on the additional sections. It does take time . . . ." *Id.* ¶ 117.

- Samsung is "[t]he largest contract manufacturer in the world of biologics." *Id.*

- "In July 2022, Checkpoint successfully completed two pre-BLA meetings with the FDA (chemistry, manufacturing and controls [CMC] and clinical/non-clinical)." *Id.* ¶¶ 122, 130.

- Checkpoint has "ha[d] the FDA involved from the beginning, seeing the batches that we've run and the assays we've developed." *Id.* ¶ 127.

- "[W]e completed our mid-cycle communication meeting with the FDA, whereby the FDA communicated no significant review issues and no safety concerns identified to date." *Id.* ¶ 137.

- "We had our mid-cycle meeting with the FDA, whereby they conveyed to us that there were no significant issues, no safety concerns thus far with the BLA review, so very clean bill of health as of that point in time with the FDA. And now we've entered into the labeling discussion, part of the BLA process . . . ." *Id.* ¶ 141.

- "Our contract manufacturer for cosibelimab has received certain observations from the FDA on Form 483." *Id.* ¶ 144.

As to these statements, the AC makes only generalized, conclusory allegations of falsity. The AC does not allege that defendants misled investors in their representations about the scale of Samsung's manufacturing facility, its experience, the duration for which Checkpoint had worked on the cosibelimab BLA, the fact of Checkpoint's discussions with the FDA before it submitted the BLA, or that the FDA, at its mid-cycle meeting, had not communicated any "significant review" or "safety" issues. The AC lacks any particularized allegations that any of these statements were false. *See, e.g.*, *Rombach*, 355 F.3d at 174 (to plead a claim of securities fraud, plaintiffs "must do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so").

The AC does suggest that Oliviero's statements as to the mid-cycle meeting, which occurred *before* August 14, 2023, falsely implied that the FDA had made statements disclaiming a regulatory risk. But the Form 483 did not issue until weeks later, on September 1, 2023. And Oliviero's statements as to the mid-cycle meeting necessarily captured only the FDA's view "as of that point in time." *Id.* ¶ 141; *see also id.* ¶ 137 (similarly qualifying). A reasonable investor would understand that caveat—that it was possible for regulatory pitfalls to arise later in time. *See, e.g.*, *Gagnon v. Alkermes PLC*, 368 F. Supp. 3d 750, 770 (S.D.N.Y. 2019) (declining to

consider statements "in a vacuum" and looking, instead, to "remarks surrounding the purportedly false or misleading statements").

The AC thus fails to adequately plead falsity.

B. Scienter

1. Applicable Law

A complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). "For an inference of scienter to be strong, 'a reasonable person [must] deem [it] cogent and *at least as compelling* as any opposing inference one could draw from the facts alleged,'" and "the court must take into account plausible opposing inferences." *ATSI Commc'ns*, 493 F.3d at 99 (quoting *Tellabs*, 551 U.S. at 324) (alteration and emphasis in original). The "inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314. The requisite mental state is one "embracing intent to deceive, manipulate, or defraud." *Id.* at 319 (internal quotation marks and citation omitted).

A complaint "may satisfy this requirement by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI Commc'ns*, 493 F.3d at 99. Where a complaint does not sufficiently allege that defendants had a motive to defraud the public, it "must produce a stronger inference of recklessness." *Kalnit v. Eichler*, 264 F.3d 131, 143 (2d Cir. 2001). A complaint can plead recklessness by adequately alleging that "defendants knew facts or had access to non-public information contradicting their public statements" and therefore "knew or should have known they were misrepresenting material facts." *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 76 (2d Cir. 2001) (citing *Novak*, 216 F.3d at 308). But

"to adequately plead scienter, plaintiffs must also provide sufficient factual allegations to indicate that defendants understood that their public statements were inaccurate, or were 'highly unreasonable' in failing to appreciate that possibility." *In re Sanofi*, 87 F. Supp. 3d at 534 (quoting *Novak*, 216 F.3d at 308). "The key, of course, is the honest belief of the management in the truth of information issued to the public." *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008), *aff'd sub nom. State Univ. Ret. Sys. of Ill. v. Astrazeneca PLC*, 334 F. App'x 404 (2d Cir. 2009).

2. Application

a. Motive

The AC pursues offer three theories of motive: that Oliviero (1) artificially inflated his incentive compensation; (2) enriched himself through suspicious transactions in Checkpoint stock; and (3) sought to ensure the success of direct offerings of Checkpoint stock. None comes close to adequately pleading scienter.

i. Oliviero's Incentive Compensation

The AC alleges that Oliviero's incentive compensation structure supports inferring his scienter. AC ¶¶ 179–81. It suggests that, because this component of his annual compensation stood to grow depending on financial metrics such as Checkpoint's stock price, total shareholder return, and market capitalization, Oliviero was incented to artificially inflate Checkpoint's stock price by concealing grave regulatory risks.

A wall of case law blocks that argument. As the Second Circuit has explained: "If scienter could be pleaded solely on the basis that defendants were motivated because an inflated stock price or improved corporate performance would increase their compensation, virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions." *ECA*, 553 F.3d at 201; *see also, e.g.*, *id.* at 198 ("Motives that

are common to most corporate officers, such as the desire for the corporation to appear profitable and the desire to keep stock prices high to increase officer compensation, do not constitute 'motive' for purposes of this inquiry."); *Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 54 (2d Cir. 1995) ("[I]ncentive compensation can hardly be the basis on which an allegation of fraud is predicated." (quoting *Ferber v. Travelers Corp.*, 785 F. Supp. 1101, 1107 (D. Conn.1991))); *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009) (bare allegation of "goals that are possessed by virtually all corporate insiders, such as the desire to sustain the appearance of corporate profitability . . . or the desire to maintain a high stock price in order to increase executive compensation" does not suffice); *Kalnit*, 264 F.3d at 142 (similar). The Court thus puts aside the AC's allegation that Oliviero's compensation structure supports an inference of scienter.

ii. Oliviero's Stock Trading Activity

The AC next tries to infer scienter from the fact that Oliviero sold Checkpoint stock on seven occasions and transferred Checkpoint stock to a trust for his children during the Class Period. AC ¶¶ 172–75. "Unusual insider sales at the time of the alleged withholding of negative corporate news may permit an inference of bad faith and scienter." *Scholastic Corp.*, 252 F.3d at 74 (quotation marks omitted). "Factors considered in determining whether insider trading activity is unusual include the amount of profit from the sales, the portion of stockholdings sold, the change in volume of insider sales, and the number of insiders selling." *Id.* at 74–75.

Here, however, the AC's allegations as to Oliviero's sales and transfer of Checkpoint stock do not support, and in some respects undermine, the notion that Oliviero sought to take advantage of allegedly fraudulently inflated market prices. That is so for multiple reasons.

First, as pled, Oliviero's holdings of Checkpoint stock *increased* during the Class Period.[8] That strongly undermines the AC's scienter theory. If Oliviero had aimed to enrich himself by selling Checkpoint's shares while temporarily fraudulently inflated, it would have made little economic sense for him to increase his holdings before the share price inevitably plummeted upon the FDA's denial (ostensibly anticipated by Oliviero) of the cosibelimab BLA. The AC attempts to elude this conclusion by stating that "many" of Oliviero's shares were "subject to delayed vesting schedules," AC ¶ 173, but, notably, it does not allege that the vesting schedule wholly prevented him from decreasing his overall holdings of Checkpoint stock during the Class Period.[9] *See Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 588, 593 (S.D.N.Y. 2011) ("It defies reason that an entity looking to profit on a fraudulently inflated stock price would hold close to ninety percent of its shares as prices fell, while knowing that the information illuminating the fraud was seeping into the market."); *Hubiack v. Li-Cycle Holdings Corp.*, No. 23 Civ. 9894, 2024 WL 2943959, at *9 (S.D.N.Y. June 10, 2024) (same).

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[8] As of April 4, 2022—the earliest date on which his ownership is pled—Oliviero owned 2,873,291 Checkpoint shares. AC ¶ 173. On December 6, 2022, Checkpoint effected a 1-for-10 reverse stock split. AC ¶ 175; Spencer Decl., Ex. B. As of August 16, 2023—the latest date on which his ownership is pled—Oliviero owned 381,580 shares of Checkpoint (equivalent to 3,815,800 shares on a pre-split basis under the AC's methodology). Spencer Decl., Ex. C; AC ¶ 175; *see also* Pls. Br. at 21 n.6. *See generally* U.S. Sec. & Exch. Comm'n, *Reverse Stock Splits*, https://www.investor.gov/introduction-investing/investing-basics/glossary/reverse-stock-splits [https://perma.cc/MFF8-RM6Q] ("When a company completes a reverse stock split, each outstanding share of the company is converted into a fraction of a share. For example, if a company declares a one for ten reverse stock split, every ten shares that you own will be converted into a single share.").

[9] Even assuming *arguendo* that the vesting schedule prevented Oliviero from decreasing his overall holdings of Checkpoint stock during the Class Period—and the AC does not plead so—his stock trading activity does not support a motive to defraud, because, as noted below, the AC does not plead anything "unusual" about the timing, volume, or value of the trades. *See Scholastic Corp.*, 252 F.3d at 74–75.

Second, the value and volume of shares that Oliviero sold, relative to his total holdings, was modest to de minimis. *See* AC ¶ 173. The most significant sale, on June 17, 2022, represented only 8.03% of Oliviero's holdings at the time. *See Acito*, 47 F.3d at 54 (sale representing less than 11% of defendant's holdings did not support strong inference of intent to deceive); *Cozzarelli v. Inspire Pharms. Inc.*, 549 F. 3d 618, 628 (4th Cir. 2008) (same, for sales representing 13% of holdings). Moreover, although the AC alleges that Oliviero's sales generated $512,644.55 in gross proceeds during the Class Period, it does not allege that these sales generated any unusual profits for him. Potentially suggesting otherwise, Checkpoint's share price as of four of the sales ($1.09–$1.11), which accounted for approximately 70% of shares sold by Oliviero, AC ¶ 173, was substantially *lower* than it was after the December 2023 announcement of the FDA's denial of the cosibelimab BLA ($1.54)—*i.e.*, when the alleged fraud came to light. *See In re Scholastic*, 252 F.3d at 74-75; *In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 271 (S.D.N.Y. 2009). On inspection, thus, the circumstances of Oliviero's stock sales do not coherently support the scienter claim.

Third, the timing of the stock sales was not suspicious. "The prototypical example of a pattern of stock sales reflecting the requisite intent involves sales shortly before the public disclosure of negative information." *In re Avon Prods., Inc. Sec. Litig.*, No. 5 Civ.6803, 2009 WL 848017, at *22 (S.D.N.Y. Feb. 23, 2009), *report and recommendation adopted*, 2009 WL 10698359 (S.D.N.Y. Mar. 18, 2009). In contrast, the sales here occurred six months before Checkpoint submitted the cosibelimab BLA to the FDA, more than a year before the FDA's inspection of Samsung, and 18 months before Checkpoint announced the FDA's denial. Such "an attenuated gap between stock sales and corrective disclosures saps an inference of scienter." *Hubiack*, 2024 WL 2943959, at *9; *see also, e.g.*, *Woolgar v. Kingstone Cos.*, 477 F. Supp. 3d

193, 235 (S.D.N.Y. 2020) ("Courts in the Second Circuit have found that stock sales are not indicative of scienter when they are more than two months before the announcement in question."); *In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 271 (S.D.N.Y. 2009) ("Plaintiffs' allegations are empty vessels, as the trades occurred . . . many months before the release of any negative information that caused Gildan's stock price to plummet."); *In re Take-Two Interactive Sec. Litig.*, 551 F. Supp. 2d 247, 275 (S.D.N.Y. 2008) (similar). The AC thus does not non-conclusorily plead that "there was something unusual or suspicious about the timing of the . . . sales." *In re CRM Holdings, Ltd. Sec. Litig.*, No. 10 Civ. 975, 2012 WL 1646888, at *23 (S.D.N.Y. May 10, 2012).

Finally, Oliviero's transfer of Checkpoint stock to an irrevocable trust for his minor children does not support that he intended to deceive investors. AC ¶ 175; *see* Spencer Decl., Ex. B. The AC does not concretely allege that the trust ever sold the stock Oliviero transferred. To the extent the trust retained the Checkpoint stock transferred to it, Oliviero's family was in no different economic circumstances than before the transfer. The AC speculates that the trust must have sold stock, because the trustee owed a fiduciary duty to prudently manage trust assets which would have caused her to "promptly s[ell] most or all of such Checkpoint stock." AC ¶ 176. But that is an *ipse dixit*. The AC's assumption that it would have been "highly imprudent" to hold Checkpoint stock after the transfer, *id.*, is undercut by its theory that defendants had duped investors (presumably including the trustee) to overestimate cosibelimab's prospects for FDA approval. *See* Spencer Decl., Ex. B ("Oliviero is not a trustee of the trust and has no investment control over the securities held by the trust."); *In re Avon Prods.*, 2009 WL 848017, at *21 (defendant's gifting shares to wife "inconsistent with plaintiffs' theory of fraudulent intent").

The AC's allegations as to Oliviero's transactions in Checkpoint stock thus do not plausibly support inferring scienter.

iii. Stock Offerings

The AC's final theory of motive is that Oliviero concealed bad regulatory developments to ensure a high share price for Checkpoint's sales offerings. Plaintiffs argue that Checkpoint lacked any FDA-approved products during the Class Period and thus depended on raising outside capital to cover its operating expenses. As a result, they argue, Oliviero had an incentive to conceal negative information about the prospects of FDA approval, to maximize Checkpoint's fundraising capacity.

This argument fails because Checkpoint's alleged need for outside capital is "too generalized to demonstrate scienter." *Kalnit*, 264 F.3d at 139–40. As courts have recognized, "[i]t is very common for companies to have secondary [offerings], and any officer or director would wish the stock price to be as high as possible during such [an offering]." *Id.*; *see also, e.g.*, *In re Emex Corp. Sec. Litig.*, No. 1 Civ. 4886, 2002 WL 31093612, at *6 (S.D.N.Y. Sept. 18, 2002) ("[A] desire to raise much needed capital is an insufficient generalized motive to support an inference of scienter." (internal quotation marks omitted)); *Russo v. Bruce*, 777 F. Supp. 2d 505, 520 (S.D.N.Y. 2011) (desire to "inflate the price of [the Company's] stock so that the Company could sell such stock to raise cash comfortably fits within the set of universal corporate motivations that are inadequate to sustain a securities fraud complaint"); *Geiger v. Solomon-Page Grp.*, 933 F. Supp. 1180, 1189–90 (S.D.N.Y. 1996) ("[A] company issuing its stock to the public always has a generalized motive to ensure the success of the issue and to raise as much money as possible."); *Inter-Local Pension Fund GCC/IBT v. Deleage* (*In re Rigel Pharms., Inc. Sec. Litig.*), 697 F.3d 869, 884 (9th Cir. 2012) ("[A]llegations of routine corporate objectives such as the desire to obtain good financing and expand are not, without more,

sufficient to allege scienter."); *cf. San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Co., Inc.*, 75 F.3d 801, 814 (2d Cir.1996) (motive to defraud not supported by allegations that company sought to "maximize the marketability of the $700 million of debt securities [it had] issued . . . and minimize the interest rate on those securities").

Furthermore, that Checkpoint's operating expenses allegedly exceeded its revenues between 2020 and 2023—when it was trying to bring cosibelimab to market—does not distinguish Checkpoint from other early-stage companies. AC ¶ 25. The AC's superficial balance sheet analysis accords with what Checkpoint's SEC filings consistently told investors: "Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given." *Id.* ¶ 27. Virtually every early-stage company "need[s] to raise money to fund its operations. . . . But a strong inference of fraud does not arise merely from seeking capital to support a risky venture." *Cozzarelli*, 549 F. 3d at 627. Ensuring that the company remains a going concern is "just an example of a generalized motive that any officer or director who desires to operate a successful company will have." *AstraZeneca*, 559 F. Supp. 2d at 469; *cf. Cozzarelli*, 549 F.3d at 627 ("All investments carry risk, particularly in a field like biopharmaceuticals. If we inferred scienter from every bullish statement by a pharmaceutical company that was trying to raise funds, we would choke off the lifeblood of innovation in medicine by fueling frivolous litigation—exactly what Congress sought to avoid by enacting the PSLRA.").

The AC's allegations as to Checkpoint's fundraising thus do not support an inference of scienter, either.

b. Conscious Misbehavior or Recklessness

Because the AC fails to plead motive, it bears a "correspondingly greater" burden in alleging conscious misbehavior or recklessness. *ECA*, 553 F.3d at 198–99 (quotation marks omitted). It does not come close to carrying that burden.

The AC's principal theory along these lines is that defendants, by concealing that the FDA had issued 11 Form 483s to Samsung from 2016 to 2023, knowingly misled the market about Checkpoint's prospects for receiving FDA approval to market cosibelimab. But, as noted, the AC does not plead a factual basis for its key inference: that Oliviero, or anyone at Checkpoint, knew of the Form 483s before making the statements at issue. And that overarching deficiency is compounded by multiple other shortcomings in the AC.

First, 10 of the 11 Form 483s that defendants allegedly concealed concerned unnamed biologics drugs that Samsung manufactured for clients *other than* Checkpoint. The AC does not allege that Samsung ever notified defendants about those reports, that defendants knew of them, or that defendants reviewed their contents before making the challenged statements. The AC does not cite any internal Checkpoint documents, or confidential witness statements, to that effect. Nor does it allege any communication from Samsung ostensibly putting Checkpoint on notice—of these forms or of facts making its public statements misleading when made. The AC does *not* allege that Checkpoint was a "client" whom Samsung Biologics notified about the "MSAT laboratory deficiency" or that defendants knew of the "internal investigation at Samsung Biologics and its firing of multiple executives." AC ¶ 149. These telling "omissions and ambiguities count against inferring scienter." *Tellabs,* 551 U.S. at 326.[10]

[10] The AC speculates that the SBS news report would have drawn Checkpoint's attention to the February 28, 2023 Form 483, but its allegations about that report are internally contradictory. Although the AC states that the news report "appears to provide" information about an FDA

Second, the AC's allegations do not support the implication that Samsung's receipt of the non-Checkpoint Form 483s was so significant a development that it assuredly would have alerted other clients, like Checkpoint, to it. Form 483s "are merely observational in nature, and do not represent the FDA's final word." *In re Genzyme,* 754 F.3d at 42; *see* AC, Ex. 4 ("[T]his document does not represent a final agency determination regarding your compliance.").[11] And the AC does not allege that the non-Checkpoint Form 483s resulted in an OAI designation, the denial of a pending BLA, a final FDA determination that Samsung was out of compliance, or any other adverse FDA action. *See supra* at pp. 31–32. Nor does the AC cite facts making the particular observations in the non-Checkpoint Form 483s so operationally "significant" for Checkpoint, AC ¶ 71, to make it is likely that Samsung shared these with Checkpoint. On the contrary, it elsewhere pleads that only an OIA designation—not the other two possible outcomes—results in a recommendation of regulatory action. *Id.* ¶ 89. The AC also does not allege that the biologics drugs for which Samsung received the non-Checkpoint Form 483s represented more than a de minimis share of the biologics drugs that Samsung manufactured.[12]

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inspection, AC ¶ 82, in the next paragraph, it attributes this perception to a "client," *id.* ¶ 83, not to any person at Checkpoint. It alleges that "*a client*, an overseas pharmaceutical company, flagged issues with the lab practice from the MSAT division of Samsung Bio during the second half last year. High executives [sic] of Samsung Bio visited the lab and found issues, which prompted a comprehensive internal investigation." *Id.* (emphasis added). The timeframe identified by the article—"second half" of 2022—is also inconsistent with the AC's speculation that the news report related to the February 28, 2023 Form 483. *See also id.* Exs. 6–7.

[11] Courts have widely recognized that a Form 483 represents "interim FDA feedback." *Schaeffer*, 2020 WL 7701463, at *9; *see also, e.g.*, *KV Pharm. Co.*, 679 F.3d at 982–83; *In re Sanofi*, 87 F. Supp. 3d at 541–42 (similar); *In re Discovery Lab'ys*, 2007 WL 789432, at *4; *McClain*, 111 F. Supp. 3d at 1304–05.

[12] To the extent it addresses the scale of Samsung's manufacturing activities, the AC quotes Oliviero's statement that Samsung is "the largest contract manufacturer in the world of biologics." AC ¶ 127.

As such, it does not support that these notices presented an existential issue for Samsung, of the sort that conceivably might have caused word of a systemic issue at Samsung to reach unaffected clients. Finally, the AC does not plead that analysts covering the pharmaceutical industry, or major biopharmaceutical companies that contracted with Samsung, viewed Samsung's receipt of Form 483s as a material regulatory event. The AC's allegations, in sum, do not support the inference that the deficiencies observed at the plant were other than finite, limited, low-profile, and redressable. They do not contribute to a strong inference of scienter.

Third, even as to the single Checkpoint-related Form 483, dated September 1, 2023, the AC does not allege that Samsung notified defendants of it before Oliviero made the statements later that month (on September 11 and 28) that the AC challenges. *See* AC, Ex. 4. The AC does not allege that Checkpoint had personnel on site at Samsung during the FDA's inspection (which was between August 21 and September 1, 2023). The AC terms the inspection "pre-announced," *id.* ¶ 84, but it does not allege that the FDA gave pre-inspection notice to *Checkpoint*, as opposed to Samsung, the entity whose property was inspected. Nor does it allege facts supporting that Checkpoint was copied on, or otherwise had real-time access to, communications between Samsung and the FDA inspectors. The AC thus lacks factual allegations for its critical premise: that Oliviero knew of the Form 483 before September 11 and 28, 2023. The AC is also devoid of concrete allegations that defendants received the EIR that it faults defendants for not mentioning in their September and November 2023 statements. AC ¶ 89; *id.*, Ex. 5. And it is not intuitively obvious why Checkpoint would have had visibility into such matters. The FDA's inspection of Samsung covered "multiple products" by multiple sponsors. *Id.* ¶ 84. There is no basis to believe the inspection targeted Samsung's work for Checkpoint. And the AC does not allege that the potential violations found at the facility, as described in the Form 483, specially

affected Checkpoint products.[13] *See, e.g.*, *Fort Worth Employers' Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 226 (S.D.N.Y. 2009) ("The mere allegation that defendants failed to disclose [relevant information] does not in and of itself constitute strong evidence that they did so with scienter."); *In re Sanofi*, 87 F. Supp. 3d at 541–42 (inference of scienter not supported by allegations that defendants did not disclose FDA's interim feedback "just because it would be of interest to investors"); *In re Genzyme*, 754 F.3d at 41–42 (similar).

Fourth, the fraud scheme that the AC envisions within Checkpoint—to conceal the fact that the Form 483 presented an insurmountable obstacle, as opposed to a readily clearable regulatory hurdle—is not coherent. On the AC's premise, defendants "would have known that" it "would be revealed, in relatively short order, upon the FDA's rejection of the" cosibelimab BLA. *Gillis*, 197 F. Supp. 3d at 600–01. As the Ninth Circuit has put the point: "[T]he notion that a company would promise [regulatory] approval that it knew would not materialize does not, without more, create a strong inference of intent to deceive or deliberate recklessness" because it "does not resonate in common experience," and "the PSLRA neither allows nor requires" courts "to check [their] disbelief at the door." *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 415 (9th Cir. 2020); *accord In re GeoPharma, Inc. Sec. Litig.*, 411 F. Supp. 2d 434, 446 n. 83 (S.D.N.Y. 2006) (collecting cases in this District). On the facts pled, the inference is far more plausible that, with the PDUFA goal date for cosibelimab more than three months away as of September 2023, and with no other regulatory hiccups yet identified, defendants did not aim to defraud when Oliviero

[13] The fact that as of Checkpoint's November 13, 2023 statement, the FDA had published the Form 483 on its website further undermines plaintiffs' claim of scienter. Jaffe Decl., Ex. 13. "It is not plausible, much less indicative of a strong inference of scienter, that" defendants acted to deceive in not referencing information that was "publicly available" at the time. *Lau v. Opera Ltd.*, 527 F. Supp. 3d 537, 557-58 (S.D.N.Y. 2021); *accord Glaser*, 772 F. Supp. 2d at 588; *In re Xunlei Ltd. Secs. Litig.*, No. 18 Civ. 467, 2019 WL 4276607, at *32 (S.D.N.Y. Sept. 10, 2019).

stated that the FDA approval process was progressing "very well" and "nicely." AC ¶¶ 137, 141. And the AC does not allege facts supporting that, had Oliviero known of the Form 483 as of September, he would have appreciated that Samsung could not bring its facility into compliance in time for Checkpoint to meet the January 3, 2024 PDUFA goal. "Courts regularly refuse to infer scienter . . . when confronted with . . . illogical allegations." *Gillis*, 197 F. Supp. 3d at 600–01; *see, e.g.*, *In re GeoPharma, Inc. Sec. Litig.*, 411 F. Supp. 2d at 446 ("[T]he tenuous plausibility of the alleged scheme substantially weakens the overall strength of plaintiffs' scienter allegations."); *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014); *Cozzarelli*, 549 F.3d at 628. Such is the case here.

Plaintiffs, finally, argue that three other facts pled in the AC support inferring scienter: (1) Oliviero's familiarity as CEO with Checkpoint's business; (2) industry practice, and (3) Checkpoint's contract with Samsung. None advances plaintiffs' claim of scienter.

Oliviero's role as CEO: Plaintiffs argue that CEO Oliviero's public statements about Checkpoint's business during the Class Period reveals his familiarity with the FDA's review process. From this, they argue, he must have known in real time of Samsung's FDA problems and that these made Checkpoint's statements about the likelihood of receiving regulatory approval misleading or false. Pl. Br. at 13. That argument fails for multiple reasons.

First, Oliviero's cited public statements overwhelmingly did not concern Samsung's regulatory track record or FDA interactions. The statements instead were high-level, general business updates touting Checkpoint's progress toward marketing cosibelimab. *See, e.g.*, AC ¶¶ 107, 117, 123, 127, 137. That a CEO would express optimism and highlight the prospects of its product candidate does not support the inference that he knew about Samsung's FDA issues with respect to other companies' products. *See, e.g.*, *In re Canopy Growth Sec. Litig.*, No. 23

Civ. 4302 (PAE), 2024 WL 3445436, at *14 (S.D.N.Y. July 17, 2024), *appeal withdrawn*, No. 24-2121, 2024 WL 4763225 (2d Cir. Oct. 9, 2024). And that Oliviero's optimism proved "unwarranted is not circumstantial evidence of conscious fraudulent behavior or recklessness." *Rothman v. Gregor*, 220 F.3d 81, 90 (2d Cir. 2000); *see also Novak*, 216 F.3d at 309. Nor does the AC support its attempted portrait of Oliviero as having held himself out as clairvoyant with respect to potential regulatory hurdles for the cosibelimab BLA. At most it supports that Oliviero later collaborated with Samsung to address the compliance issues that cosibelimab BLA encountered *after* the CRL issued in late December 2023. *See* AC ¶¶ 155–58 (January 18, 2024 statement in response to analyst question "about the FDA's complete response letter for the cosibelimab BLA").

Second, the AC's attempt to derive scienter from the fact that a defendant is a "key officer" well versed in a company's business is undermined by the assembled case law, which rejects the premise of *ex officio* omniscience of all business risks. *See In re ShengdaTech, Inc. Sec. Litig.*, No. 11 Civ. 1918, 2014 WL 3928606, at *9 (S.D.N.Y. Aug. 12, 2014) (collecting cases). As those cases reflect, a claim like that here—that Oliviero, by dint of being CEO, should have known that Samsung's manufacturing practices presented an obstacle to regulatory approval for cosibelimab—is a classic, and impermissible, one of "fraud by hindsight." *In re Express Scripts Holdings Co. Sec. Litig.*, 773 F. App'x 9, 14 (2d Cir. 2019); *see Denny v. Barber*, 576 F.2d 465, 470 (2d Cir. 1978).

Third, contrary to plaintiffs' claim, Pls.' Br. at 8, that Oliviero signed Checkpoint's SEC filings, does not prove his scienter. That argument "would allow plaintiffs to plead the scienter of whole classes of defendants solely by alleging a misstatement." *In re Marsh & McLennan Cos. Sec. Litig.*, 501 F. Supp. 2d 452, 485 (S.D.N.Y. 2006); *see also Zhong Zheng v. Pingtan*

Marine Enter. Ltd., 379 F. Supp. 3d 164, 181 (E.D.N.Y. 2019) (collecting cases holding that signing SEC filings "add nothing substantial to the scienter calculus").

Industry practice: As a basis for scienter, the AC also cites what it terms "industry standard practice." AC ¶¶ 53–69. Its allegations to this effect come from (1) a former Samsung employee, Ronald Marchesani, and (2) a declaration by a "regulatory consultant," Jennifer Ahearn. *Id.* ¶¶ 53, 58.

Marchesani's statements do not support a strong inference of scienter. As pled, he never worked at Checkpoint, and although a senior Samsung employee between 2015 and 2018, he left Samsung more than three years before the start of the Class Period and some five years before the central event in this case: the FDA's late August 2023 inspection of Samsung in connection with the cosibelimab BLA. *Id.* ¶ 59. As pled, he thus lacks both firsthand knowledge of Checkpoint and fresh information about Samsung. His observations thus cannot bear upon defendants' state of mind in making the challenged statements. And the AC admits that Marchesani did not perform "any work relating to Checkpoint during his time at Samsung Biologics." *Id.* ¶ 69. It does not allege he ever had any personal knowledge, even dated, as to the business relationship between Samsung and Checkpoint. The AC's allegations do not "support the probability that a person in [Marchesani's] position . . . would possess the information alleged." *Novak*, 216 F.3d at 314. Assessments by a witness whose basis for knowledge is ill-pled must be discounted. *See, e.g.*, *Glaser*, 772 F. Supp. 2d at 589–95.

Indeed, even had the AC ably pled that Marchesani had some general knowledge bearing on Checkpoint, to plead defendants' scienter based on asserted conflict between what defendants knew and what they said, a complaint would have to plead more: "specific instances" in which the defendants "received information . . . contrary to their public declarations." *Plumbers &*

Steamfitters Local 773 Pension Fund v. Canadian Imperial Bank of Com., 694 F. Supp. 2d 287, 299 (S.D.N.Y. 2010); *see also In re Gentiva Sec. Litig.*, 971 F. Supp. 2d 305, 324 (E.D.N.Y. 2013) (collecting cases). "[E]ven confidential high level executives' statements will be insufficient absent some allegation that the witness communicated with the individual defendants claimed against in the case, or else that the witness was privy to the individual defendants' knowledge." *Glaser*, 772 F. Supp. 2d at 589–90; *Ap-Fonden v. Gen. Elec. Co.*, No. 17 Civ. 8457, 2021 WL 311003, at *8 (S.D.N.Y. Jan. 29, 2021) (complaint must "describe the nature of the [witness's] contact with the individual defendants that would be probative of defendants' mental state"). The AC lacks such allegations.

Ahearn is a former FDA analyst who left the agency in 2008 and has since worked as a consultant.[14] Her declaration, attached to the AC, opines on "industry standard practices relating to the relationship between sponsors of FDA Biologics License Applications (BLAs) and their contract manufacturing organizations (CMOs), and the extent of communication and cooperation between sponsors and their CMOs with respect to FDA pre-approval inspections." AC, Ex. 3 ¶ 3. But the observations attributed to her do not support scienter.

At the pleading stage, expert "opinions cannot substitute for facts under the PSLRA" "unless [the] opinion was based on particularized facts sufficient to state a claim for fraud." *Ark. Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343, 354 (2d Cir. 2022) (quoting *Fin. Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 286 (5th Cir. 2006)). The Ahearn Declaration is not based on particularized allegations of fact. It instead makes generic statements

[14] Ahearn holds herself out as a regulatory consultant who "help[s] industry exceed regulatory compliance requirements, while maintaining practical manufacturing." AC, Ex. 3, at 8. She was employed as a "chemist/investigative analyst" at the FDA from June 2002 to November 2008. *Id.* at 11.

about "industry practice" that conclusorily restate the AC's allegations to that effect. *See Omnicare*, 575 U.S. at 183; *see also, e.g.*, *Loc. No. 38 Int'l Bhd. of Elec. Workers Pension Fund v. Am. Express Co.*, 724 F. Supp. 2d 447, 462 (S.D.N.Y. 2010) ("[B]land assertions that they 'would have received' such information offer nothing concrete and are not allegations of fact."), *aff'd*, 430 F. App'x 63 (2d Cir. 2011); *Singh v. Deloitte LLP*, No. 21 Civ. 8458, 2023 WL 4350650, at *6 (S.D.N.Y. July 5, 2023) (similar), *aff'd*, 123 F.4th 88 (2d Cir. 2024). Critically here, the AC's allegations based on the Declaration do not derive from any personal knowledge on Ahearn's part of the events at issue in this case. Ahearn does not claim to have ever engaged with or consulted for Checkpoint or Samsung, intermediated between the two, or been involved in dealings between Samsung and the FDA. Her observations instead are based on her experience "develop[ing] and manag[ing] quality systems from the ground up," AC, Ex. 3 ¶ 1, but she offers no factual basis to infer that those systems are comparable to that used by Checkpoint for cosibelimab. Her suppositions here do not have any bearing on defendants' scienter. *See Bristol-Myers Squibb*, 28 F.4th at 354 (allegations based on purported expert opinion did not add support to inference of scienter where "the only facts on which [the expert] relied" were the complaint's otherwise "insufficient" allegations); *Singh v. Deloitte LLP*, 123 F.4th 88, 95 n.9 (2d Cir. 2024) ("opinion [did] not rescue a deficient pleading" where it was "simply a conclusory statement of the plaintiff's argument." (internal quotation marks omitted)); *McKenna v. SMART Technologies Inc.*, No. 11 Civ. 7673, 2012 WL 3589655, at *5 (S.D.N.Y. Aug. 21, 2012).[15]

[15] Defendants separately move to strike the Ahearn Declaration, on the ground that its physical annexation to the AC, without more, does not permit it to be considered on a motion to dismiss. In light of the Court's discounting the Declaration as irrelevant, the Court need not resolve the motion to strike. Defendants' argument, however, is substantial. Courts may consider materials

Checkpoint's contract with Samsung: Finally, the AC alleges that, under the Master Services Agreement (the "MSA"), its contract with Samsung, Checkpoint had the right to "access" Samsung's manufacturing facility. AC ¶ 32(e); *see also id.* ¶¶ 6, 32–33. Plaintiffs argue that, once Samsung's compliance with cGMP regulations arose as an issue with respect to FDA review of the cosibelimab BLA, defendants surely availed themselves of this right, and thereby learned of the extent of Samsung's compliance issues. *See* Pls.' Br. at 14–15.

Defendants dispute plaintiffs' interpretation of the MSA. But even crediting the AC's claim, this theory of scienter fails. That is because the AC does not allege that Checkpoint in fact exercised its purported right of access before making the statements the AC challenges, let alone that in connection with exercising its right of access, Checkpoint learned information that was inconsistent with its later statements. Even assuming that Checkpoint personnel visited the facility, on the facts pled, there would not have been specific cause for such a visit until after Checkpoint learned of the Checkpoint Form 483, and such a visit could well have occurred after defendants' challenged statements. And the AC's conjecture as to the information gleaned

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extrinsic to a complaint, but such must be incorporated by reference into the complaint or otherwise be integral to it, *Gant v. Wallingford Bd. of Educ.*, 69 F.3d 669, 674 (2d Cir. 1995). Under Fed. R. Civ. P. 10(c), affidavits attached to a complaint do not, on that basis, qualify as "written instruments" that may be considered. *Smith v. Hogan*, 794 F.3d 249, 254 (2d Cir. 2015); *Ong v. Chipotle Mexican Grill, Inc.*, 294 F. Supp. 3d 199, 223 (S.D.N.Y. 2018). For a document to be incorporated into a complaint by reference, a plaintiff must "rely on the terms and effect of the document in drafting the complaint." *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 231 (2d Cir. 2016) (quoting *Global Network Commc'ns, Inc. v. City of New York*, 458 F.3d 150, 156 (2d Cir. 2006)). "Merely mentioning a document in the complaint will not satisfy this standard[.]" *Goel v. Bunge, Ltd.*, 820 F.3d 554, 559 (2d Cir. 2016). In *Ong*, for example, the court refused to consider an expert declaration annexed to the complaint because it "was created long after the events giving rise to [the] litigation and is thus not the type of 'written instrument' falling within the purview of Rule 10(c)." 294 F. Supp. 3d at 224 (noting that the declaration "was drafted for the purpose of this litigation" and thus plaintiffs "could not have relied on its terms while drafting their complaint.") (emphasis in original); *Singh*, 2023 WL 4350650, at *5 (similar).

during such a visit is just that—conjecture. As courts have widely held, an issuer's mere access to information alone is not tantamount to knowledge. "[I]t would make little sense to draw a strong inference of scienter from access to information. If access alone were enough, a strong inference of scienter would exist for high-level executives whenever they make a public statement contradicting something in the company's files." *Meitav Dash Provident Funds & Pension Ltd. v. Spirit AeroSystems Holdings, Inc.*, 79 F.4th 1209, 1217 (10th Cir. 2023); *see also, e.g.*, *Loc. No. 38 Int'l Bhd. of Elec. Workers Pension Fund v. Am. Exp. Co.*, 724 F. Supp. 2d 447, 462 (S.D.N.Y. 2010) (allegations that "information was the sort of [information]" that "would have been reviewed by the Individual Defendants are too speculative to give rise to a strong inference of scienter"), *aff'd*, 430 F. App'x 63 (2d Cir. 2011); *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 620 (9th Cir. 2017) (similar). That principle applies with particular force here, in that the AC's theory of access concerns information not in the issuer's records or plant, but in those of a third-party manufacturer. Checkpoint's contractual right of access does not "giv[e] rise" to a "strong" inference of scienter. 15 U.S.C. § 78u-4(b)(2).

c. Overall Assessment of Scienter

As the Supreme Court has emphasized, a court reviewing a complaint under the PSLRA should not "scrutinize each allegation in isolation," but instead must "assess all the allegations holistically." *Tellabs*, 551 U.S. at 326. The "inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id.* at 314.

Here, the AC's theories of scienter, viewed in combination, do not clear that bar—or come close. The AC does not plead any particularized facts supporting Oliviero's motive to commit the fraud. *ATSI Commc'ns*, 493 F.3d at 99. And none of the AC's varied theories

support inferring knowledge on Oliviero's part of the non-Checkpoint Form 483s. The facts alleged do make it possible that Oliviero knew of the Checkpoint-related Form 483 by the time of his September 2023 statements. But they do not plead more than a possibility of that. And they certainly do not support plaintiffs' critical inference: that, from the Form 483, Oliviero appreciated that Samsung would be unable to satisfactorily address the "observations" in the Form 483 by the PDUFA goal date, and then lied about it to investors. That inference is not cogent or compelling. The more plausible inference is that Oliviero, who did not have an affirmative duty to mention the Form 483, did not do so because he believed that cosibelimab remained on track for timely FDA approval. On the facts pled, he had sound reasons not to treat the Form 483 as more than a navigable speed bump. These included that the Form 483 was observational in nature, was issued after a "multi-sponsor inspection," and did not overtly threaten cosibelimab's PDUFA goal date. And all other data known to Checkpoint was consistent with cosibelimab's timely approval, including the FDA's endorsement of the PDUFA timetable at its mid-cycle meeting, when it last spoke to the issue. *See Tellabs*, 551 U.S. at 323, 326 (inquiry is "inherently comparative" and "omissions and ambiguities count against inferring scienter"). On the well-pled facts, plaintiffs' speculative competing inference is far less compelling than the quotidian non-actionable one: that defendants believed in good faith that they would obtain regulatory approval and commercialize cosibelimab on the anticipated timeline, and that once that schedule became unattainable, they timely updated the market.

The Court thus rejects, as inconsistent with the PSLRA, the AC's attempt to plead scienter via inadequate allegations of motive and recklessness. "[Z]ero plus zero cannot equal one." *Reilly v. U.S. Physical Therapy, Inc.*, No. 17 Civ. 2347, 2018 WL 3559089, at *19 (S.D.N.Y. July 23, 2018). The PSLRA imposes "[e]xacting pleading requirements," *Tellabs*,

551 U.S. at 313, precisely "to discourage private securities actions lacking merit" and "fishing expeditions brought in the dim hope of discovering a fraud," *Pub. Emps.' Ret. Ass'n of Colo. v. Deloitte & Touche LLP*, 551 F.3d 305, 311 (4th Cir. 2009). The AC's allegations, viewed together, do not supply strong circumstantial evidence of conscious misbehavior or recklessness. *See ATSI Commc'ns*, 493 F.3d at 99. Its § 10(b) claims, already deficient for failure to plead falsity, must separately be dismissed for failure to plead scienter.[16]

C. The AC's § 20(a) Claims

The AC also brings a claim against Oliviero under § 20(a) of the Exchange Act, based on his status as a controlling person of Checkpoint. AC ¶¶ 210–13. To make out a § 20(a) claim, a plaintiff must adequately allege "a primary violation by the controlled person." *Carpenters Pension Tr. Fund*, 750 F.3d at 236 (quoting *ATSI Commc'ns*, 493 F.3d at 108). Because the AC has not done so, its § 20(a) claim must also be dismissed. *See, e.g.*, *In re Lions Gate Entm't Corp. Sec. Litig.*, 165 F. Supp. 3d 1, 12–13 (S.D.N.Y. 2016) (dismissing § 20(a) claim based on failure to adequately allege a primary violation); *Gillis*, 197 F. Supp. 3d at 606 (S.D.N.Y. 2016) (same).

[16] The AC's claim of Checkpoint's scienter is derivative of its claim of Oliviero's scienter. Because the AC fails to plead facts giving rise to a strong inference of scienter as to Oliviero, its claims against Checkpoint thus also fail. *See Jackson v. Abernathy*, 960 F.3d 94, 98 (2d Cir. 2020) ("Where a defendant is a corporation, [a plaintiff must] plead facts that give rise to 'a strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter.'"). Plaintiffs do not suggest that this is one of those "exceedingly rare instances" of such "dramatic" fraud that "collective corporate scienter may be inferred" in the absence of scienter on the part of an individual defendant. *Id.*

CONCLUSION

For the foregoing reasons, the Court grants defendants' motion to dismiss. The Court dismisses the AC with prejudice.[17]

The Clerk of Court is respectfully directed to terminate all pending motions, to enter judgment in favor of defendants, and to close this case.

SO ORDERED.

Paul A. Engelmayer
United States District Judge

Dated: May 19, 2025
New York, New York

[17] Plaintiffs have not sought leave to amend, and the Court declines to grant such leave *sua sponte*. *Cf. Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1132 (2d Cir. 1994) ("[W]e do not deem it an abuse of the district court's discretion to order a case closed when leave to amend has not been sought."). On the contrary, lead plaintiff has already amended his complaint once, and was given another opportunity to amend his complaint after defendants filed their motion to dismiss, while being admonished that "[n]o further opportunities to amend will ordinarily be granted." Dkt. 33. And no aspect of the record suggests that repleading would remedy the deficiencies in the AC set out here. "In the absence of any identification of how a further amendment would improve upon the complaint, leave to amend must be denied as futile." *In re WorldCom, Inc. Sec. Litig.*, 303 F. Supp. 2d 385, 391 (S.D.N.Y. 2004); *see also, e.g.*, *Panther Partners Inc. v. Ikanos Commc'ns, Inc.*, 347 F. App'x 617, 622 (2d Cir. 2009) (summary order) ("Granting leave to amend is futile if it appears that plaintiff cannot address the deficiencies identified by the court and allege facts sufficient to support the claim."). "Permitting a new round of repleading in this litigation would . . . further delay already long-delayed litigation and prejudice defendants in their bid for closure." *Stanley v. City Univ. of N.Y.*, 18 Civ. 4844 (PAE), 2023 WL 2714181, at *26 (S.D.N.Y. Mar. 30, 2023); *see also, e.g.*, *Morency v. NYU Hosps. Ctr.*, 728 F. App'x 75, 76 (2d Cir. 2018) ("[T]he liberality with which a court grants leave to amend does not impart to litigants the privilege of re-shaping their legal theories endlessly." (citation omitted)).